UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

This case presents a disturbing window into a clear and present danger to the United States drug supply. The defendant manufacturers of valsartan, a medication to treat high blood pressure, elevated their pursuit of market share and profit to an unsafe and reprehensible level, and in order to do so they abrogated their fundamental obligations to protect the safety of the intended patient population. In the words of one high level executive of the API manufacturer based in China, the successful pursuit of a manufacturing process that could decrease cost and increase yield was what allowed the manufacturer to "dominate the world market" for the drug. The manufacturing processes resulted in contamination of the blood pressure medication with substances known as NDMA and NDEA, which are genotoxic, probable human carcinogens used to deliberately induce cancer in lab animals for study purposes – admitted to be so toxic that it would be "unethical" to deliberately study the effects in humans or to knowingly sell the contaminated pills. At issue on these motions, the Defendants warranted and represented that they were selling the FDA approved formulation of valsartan, but they were not. In fact, two of the defendants have been proven to have fraudulently sold the contaminated medication as the FDA approved formulation after internally confirming the contamination.

Accordingly, class Representative Plaintiff MSP via its two assignors EmblemHealth and SummaCare, on behalf of the TPP Bellwether Subclasses,[1] moves against the Defendants ZHP, Teva and Torrent[2] for partial summary judgement for the class on discrete issues as follows:

1. Express Warranty: the existence of express warranties, and breaches of same. (Damages to be determined at trial).

2. Consumer Protection Laws: violation of consumer protection laws. (Damages to be determined at trial).

3. Adulteration of the at-issue contaminated API and finished dose.

4. Violation of cGMPs in the manufacture of the at-issue contaminated API and finished dose, rendering them adulterated.

5. Failure of the at-issue contaminated API and finished dose to meet the compendial requirements for quality and safety, rendering them adulterated.

Existence and Breach of Express Warranties. ZHP, Teva, and Torrent provided express warranties that their valsartan API (in the case of ZHP) and finished-dose valsartan, or VCDs, (in the case of ZHP, Teva, and Torrent) were the FDA approved and USP compliant formulations of those products, as listed in the

[1] These subclasses are identified in Case Management Order No. 32 (ECF 2343).
[2] Defendants herein are Zhejiang Huahai Pharmaceutical Co., Ltd.; Huahai US Inc.; Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC; Solco Healthcare US, LLC (collectively "ZHP"); Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Actavis Pharma, Inc.; Actavis, LLC (collectively "Teva"); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively "Torrent").

Orange Book. Defendants breached those warranties. ZHP's valsartan API failed to match the approved formulation because it was contaminated by the nitrosamine impurities NDMA and NDEA that are admitted to be genotoxic, probable human carcinogens. Thus, the API was adulterated, not cGMP compliant, and not in conformance with compendial standards. The FDA explicitly found that ZHP's valsartan API was adulterated. ZHP's finished-dose VCDs, and Teva's and Torrent's VCDs were also adulterated by definition because those products incorporated the contaminated and adulterated valsartan API from ZHP. Each Defendant's VCDs also were not cGMP compliant or in conformance with compendial standards.

Liability Under Consumer Protection Laws. ZHP's, Teva's, and Torrent's conduct also constitutes violations of the Consumer Protection Laws ("CPL") of the states in CPL Subclass A. The states in CPL Subclass A all model their CPL statutes on the Federal Trade Commission Act and/or construe them such that the standards are the same in practice, in essence requiring a finding of deceptive or unfair practices. The Defendants' conduct was unquestionably "deceptive" and "unfair" based on the undisputed evidence, as those terms are construed by the states at issue. The states at issue in CPL Subclass A do not require any showing of intent and all other incidental elements are easily met based on undisputed facts.

ZHP and Torrent Knowingly Committed Fraud. Plaintiffs address their dispositive motions against ZHP and Torrent in the separate briefs directed to those Defendants only.

I. LEGAL STANDARD

The standard is well known to the Court. "A party may move for summary judgment, identifying each claim or defense – or the part of each claim or defense – on which summary judgment is sought. The Court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Am. Auto. Insur. Co. v. Murray*, 658 F.3d 311, 320 (3d Cir. 2011).

Moreover, "[i]f the court does not grant all the relief requested by the motion, it may enter an order stating any material fact – including an item of damages or other relief – that is not genuinely in dispute and treating the fact as established in the case." Fed. R. Civ. P. 56(g); *Murzuq v. Loury*, Civil Action No. 09–3933 (RBK), 2011 WL 2221180, *4 (D.N.J. June 6, 2011) (Kugler, J.).

II. LEGAL ARGUMENT

The undisputed factual record demonstrates that Defendants made express warranties and breached same, engaged in deceptive and unfair conduct in violation of the applicable consumer protection laws, and that the TPPs were damaged – since but for the wrongful conduct, the contaminated valsartan could not have been sold

or purchased. Granting Plaintiffs' motions in whole or in part will narrow the issues for trial, and allow the trial to proceed more efficiently and quickly to the few issues that may actually need to be determined by the factfinder.

A. Express Warranty Claims: ZHP, Teva, and Torrent Each Independently Made and Breached Express Warranties to the TPP Class Members

The Court has previously ruled that express warranties were made and breached by the manufacturers.

> In short, because of the economic reality of drug sales in the U.S., the mfr's identification of a generic drug as the chemical equivalent to the Orange Book brand name can do nothing else but constitute an express warranty … And if the generic mfr sells a contaminated drug using the generic name of an Orange Book equivalent, then a mfr can only have breached an express warranty.
>
> The issue, then, [is] whether … third party payors perceived an express warranty on the VCDs at issue, and then, based on that perceived warranty, chose to buy or fund them. The Court finds that, for prescription drugs, the mere identifying and marketing a drug as THE generic equivalent to a branded pharmaceutical listed in the Orange Book and then selling that generic equivalent when it contains a contaminant not included in the Orange Book listing constitutes a breach of express warranty. A marketed generic containing a contaminant cannot be the equivalent to the chemical entity listed in the Orange Book. Put simply, a seller cannot call its product "X" and sell it as "X" and then expect such identification not to create an express warranty that the product is "X".
>
> The Mfrs' very naming of the drug as valsartan or valsartan-containing amounted to an express warranty on which plaintiffs had no choice but to "rely" when they were prescribed the drug and bought it as a medication for

> their high blood pressure. Plaintiffs did not have to "perceive" the package labelling or insert in order to create a benefit of the bargain. All they had to know was they were buying a generic drug that contained valsartan because the very name "valsartan" or "valsartan-containing" constituted itself an express warranty that what plaintiffs were purchasing was the chemical equivalent of the Orange Book pharmaceutical.

In re Valsartan, Losartan, Irbesartan Prods. Liab. Litig., MDL No. 2875 (RBK-JS), 2021 WL 222776, at *11 (D.N.J. Jan. 22, 2021) (internal footnotes omitted) (ECF 775, at 14).

1. ZHP, Teva, and Torrent Defendants Each Independently Made Express Warranties to the TPP Class Members

The first element of a breach of express warranty claim under the laws of each state in the TPP Breach of Express Warranty Subclass Group b ("EW Subclass b") is whether the defendant made an affirmation, promise, or description about the product.[3]

[3] *Barko Hydraulics, LLC v. Shepherd*, 167 So. 3d 304, 310 (Ala. 2014); Ala. Code 1975 § 7-2-313; *Currier v. Spencer*, 772 S.W.2d 309, 311 (Ark. 1989) (citing Ark.Code Ann. § 4–2–313); *Miles v. Kavanaugh*, 350 So. 2d 1090, 1093 (Fla. Dist. Ct. App. 1977) (citing F.S.A. § 672.313); *Hill Aircraft & Leasing Corp. v. Simon*, 177 S.E.2d 803, 805 (Ga. App. 1970) (citing what is now Ga. Code Ann., § 11-2-313); *Tellus Operating Grp., L.L.C. v. R & D Pipe Co.*, 377 F. Supp. 2d 604, 611 (S.D. Miss. 2005) (quoting Miss. Code Ann. § 75–2–313); *Hirst v. Elgin Metal Casket Co.*, 438 F. Supp. 906, 907 (D. Mont. 1977) (**granting summary judgment on liability** (citing MCA 30-2-313)); *Herman v. Bonanza Buildings, Inc.*, 390 N.W.2d 536, 542–43 (Neb. 1986); *Radcliff v. Amiraslanov*, 128 Nev. 928, (2012) (citing NRS 104.2313); *Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 498 (N.H. 2005) (citing RSA 382–A:2–313); *Promuto v. Waste Mgmt., Inc.*, 44 F. Supp. 2d 628, 642 (S.D.N.Y. 1999) (**granting summary judgment** on express warranty

No reasonable dispute exists that ZHP, Teva, and Torrent each independently made affirmations or descriptions of their valsartan and VCD products. ZHP affirmatively marketed its valsartan API as US grade, FDA-approved valsartan API. (ZHP SOMF ¶ 146.5, 154.5; Torrent SOMF ¶ 37; Teva SOMF ¶ 34).[4] ZHP, Teva, and Torrent each affirmed and described their finished-dose VCDs as FDA approved "valsartan" that was the generic or therapeutic equivalent of DIOVAN® or EXFORGE®, and that their product met all compendial requirements. (ZHP SOMF ¶ 126-34, 145-54; Teva SOMF ¶ 37-40; Torrent SOMF ¶ 32, 36, 37, 57).

The above affirmations and descriptions of Defendants' VCDs amounted to express warranties, as previously found by the Court, and consistent with the laws

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liability); *Diop v. BMW of N. Am., LLC*, 511 F. Supp. 3d 679, 686 (E.D.N.C. 2021); *Darton Corp. v. Uniroyal Chemical Co.*, 917 F. Supp. 1173 , 1177 (N.D. Oh. 1996); *Oregon Azaleas, Inc. v. W. Farm Serv., Inc.*, 65 F. App'x 101, 102 (9th Cir. 2003); *Williams v. Johnson & Johnson*, 581 F. Supp. 3d 363, 372 (D.R.I. 2022); *Herring v. Home Depot, Inc.*, 565 S.E.2d 773, 776 (S.C. Ct. App. 2002); *Enpro Systems, Ltd. v. Mamasco Corp.*, 382 F. Supp. 874, 887-89 (S.D. Tx. 2005) (**granting summary judgment to the plaintiff**); *State By & Through Div. of Consumer Prot. v. GAF Corp.*, 760 P.2d 310, 314 (Utah 1988) (citing Utah Code Ann. § 70A–2–313); *DJ's Tree Serv. & Logging, Inc. v. Bandit Indus., Inc.*, 557 F. Supp. 3d 511, 532 (D. Vt. 2021) (quoting 9A V.S.A. § 2-313(1)); *Ewers v. Eisenzopf*, 276 N.W.2d 802, 805 (Wis. 1979) (discussing W.S.A. 402.313)); W.S. § 34.1-2-313; *see also* Uniform Commercial Code § 2-313.

[4] For ease of reference, Plaintiffs have filed three statements of undisputed material facts focused on the ZHP, Teva, and Torrent Defendants, respectively. However, each statement includes facts for all three Defendants, so this manner of filing does not constitute a limitation of each statement to its nominal defendant. The statements of undisputed material facts are cited as "ZHP SOMF," "TEVA SOMF," and "Torrent SOMF."

of the states in Breach of Express Warranty Subgroup b.[5]

Given the absence of any genuine factual dispute about ZHP, Teva, and Torrent's express assertions about their valsartan API or VCDs, partial summary judgment for Plaintiffs on this element is appropriate.

2. The ZHP, Teva, and Torrent Defendants Each Independently Breached Their Express Warranties

Just as an affirmation or description is an element of each applicable state's express warranty law, so, too, is whether a defendant breached its warranties.[6] ZHP, Teva, and Torrent each breached their respective express warranties for multiple reasons: their valsartan API and finished-dose VCDs were not what they purported to be, i.e., FDA-approved "valsartan", therapeutic or generic equivalents to the

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[5] *See, e.g.*, *La Trace v. Webster*, 17 So.3d 1210, 1219 (Ala. Ct. App. 2008) (statement that lamps were "Tiffany" brand lamps created express warranty);; *Walcott & Steele, Inc. v. Carpenter,* 436 S.W. 2d 820, 822 (Ark. 1969); *Karhu v. Vital Pharm., Inc.*, No. 13cv60768, 2013 WL 4047016, at *6 (S.D. Fla. Aug. 9, 2013) (applying Florida law to a pharmaceutical defendant and stating that "express warranties … were contained on the packaging and in the advertisements, both clearly directed toward the end-purchaser. Accordingly, based on the facts of this case, privity is not required to state a claim for breach of express warranty[.]"); *City of Savannah v. U.S. Fuel Corp.*, 116 S.E. 218 (Ga. App. 1923) ("words descriptive of the subject matter are ordinarily to be treated as an express warranty"); *Moore v. Puget Sound Plywood, Inc.*, 214 Neb. 14, 332 N.W.2d 212 (Neb. 1983); *Arthur Glick Leasing, Inc. v. William J. Petzold, Inc.*, 51 A.D.3d 1114, 116, 858 N.Y.S.2d 405 (NY 2008); *Pake v. Byrd*, 55 N.C.App. 551, 286 S.E.2d 588 (1982) ("In actual practice affirmations of fact made by the seller about the goods during a bargain are regarded as part of the description of those goods; hence no particular reliance on such statements need to be shown in order to weave them into the fabric of the agreement. "); *see also* Footnote 3 above.

[6] *See* Footnote 3 above.

RLDs, meeting compendial standards, manufactured in compliance with cGMPs. A non-exhaustive list of the undisputed ways in which each Defendant breached their express warranties follows.

a. ZHP's, Teva's, and Torrent's Valsartan API and VCDs Were Adulterated as a Matter of Law

Drug adulteration is statutorily defined:[7]

> **(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture…**
>
> … (2)…(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; ….
>
> **(b) Strength, quality, or purity differing from official compendium**
>
> If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. ….

21 U.S.C. §. 351(a)(2)(B), (b).

Here there is no plausible factual dispute that ZHP's valsartan API was adulterated. The FDA explicitly found that ZHP's API was adulterated in its

[7] *See* 21 U.S.C. § 351.

November 29, 2018 Warning Letter. (ZHP SOMF ¶ 47). The FDA's letter concluded, in relevant part, that ZHP's valsartan API was adulterated because it was contaminated with NDMA due to "significant" violations of cGMPs in the manufacture of the API: "Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, an Cosmetic Act, 21 U.S.C., 351(a)(2)(B)." (ZHP SOMF ¶ 47-51). This finding alone is dispositive. See *United States of America v. 286,161 Bottles et al.*, No. 19cv3876, 2021 WL 2272402, at *3-4 (N.D. Ill. May 4, 2021); *Alra Labs. v. Am. Cyanamid Co.*, No. 92cv2252, 1996 WL 377070, at *4-5 (N.D. Ill. July 2, 1996).

Further, ZHP's, Teva's, and Torrent's respective finished-dose VCDs each incorporated ZHP's adulterated valsartan API. (ZHP SOMF ¶ 23, 47-51, 164-167; Teva SOMF ¶ 1-25; Torrent SOMF ¶ 6-7, 14-15, 23, 25). Because every single pill sold by these Defendants contained adulterated valsartan API, their finished-dose VCDs were adulterated as well by statutory definition. The alternative is not logical.

The Defendants are each independently liable for breaching their express warranties by selling adulterated drugs. In fact, when ZHP tried to pass the buck, the FDA explicitly told ZHP that it was responsible for the quality of its drugs, rejecting ZHP's argument that it was not responsible because the FDA did not detect the contamination before it was disclosed, and it was too hard to detect. (ZHP SOMF

¶ 48, 50-51) (FDA stating: "You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes," "We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce," "Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance," and "You are responsible for investigating these deviations, for determining the causes, for preventing their recurrence, and for preventing other deviations."). Defendants' corporate representatives admitted that they each bore ultimate responsibility for the quality and purity of their drugs, including the API incorporated therein. (ZHP SOMF ¶ 50-51, 58, 73-74, 84; Teva SOMF ¶ 26-28; Torrent SOMF ¶ 5, 5(a), 5(b), 61). Thus, no genuine dispute exists as to whether ZHP's, Teva's, and Torrent's finished dose VCDs were adulterated by virtue of incorporating ZHP's adulterated valsartan API.

Defendants will undoubtedly lean on the conclusory testimony from their experts to dispute adulteration. For example, ZHP's expert Dr. Afnan, as well as Teva and Torrent experts, speciously argue that a drug can only be declared adulterated in the present and on a going-forward basis, rather than retrospectively. These illogical assertions are unreliable, untethered to law or facts, and ignore the many factual admissions by ZHP, Teva, and Torrent; thus, they should be rejected

as a matter of law if raised in opposition to this motion. (*See generally* ECF 2286, 2355, 2295, 2361, 2297, 2362).

b. Undisputed Evidence Establishes That The ZHP, Teva, and Torrent Defendants Independently Violated CGMPs and Could Not Assure the Quality of their Valsartan or VCDs Rendering Them Adulterated

The Court should rule that ZHP violated cGMPs, rendering the contaminated valsartan adulterated as a matter of law, based on the FDA's finding as well. The cGMP violations clearly impacted the valsartan and VCD's in question. *See United States of America v. 286,161 Bottles et al.*, No. 19cv3876, 2021 WL 2272402, at *3-4 (N.D. Ill. May 4, 2021); *Alra Labs. v. Am. Cyanamid Co.*, No. 92cv2252, 1996 WL 377070, at *4-5 (N.D. Ill. July 2, 1996).

Even absent the FDA's express finding that ZHP's valsartan API was adulterated—which in itself is dispositive as a matter of law—the undisputed record here establishes that ZHP, Teva, and Torrent each independently violated CGMPs and could not assure the quality of their respective VCDs. 21 U.S.C. § 351(a)(2)(B) (drug is adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess").

ZHP has admitted that it completely failed to consider, account for, or test with regard to the potential creation of genotoxic nitrosamines from its newly created TEA with sodium nitrite quenching and zinc chloride manufacturing processes. Instead of complying, they ignored the issue in developing the offending manufacturing processes, which were developed during the same time period, as extensively documented in discovery. For example:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

Every violation of cGMPs summarized above and in the SOMFs applies to both processes, since the same failures occurred in both, which were developed during the same time period. In fact, wherever the failure to evaluate the risks of using DMF is discussed, one could substitute TEA for DMF and apply the same analysis, and vice versa. ZHP has never asserted to the contrary, and never produced any documents to the contrary. No reasonable juror could find that ZHP did not

violate cGMPs, or that ZHP's violations of cGMP's did not result in ZHP's failure to prevent or detect the NDMA and NDEA contamination in its API and finished dose incorporating that API. *See also, e.g.*, ECF 2261, p. 21 (finding that "**It is further incontrovertible in the morass of factual and legal arguments here that the contamination resulted from defendants' non-compliance of cGMPs at some level**.") (emphasis added). This is especially so in light of the FDA's findings that ZHP's CGMP violations were "significant" and resulted in ZHP's failure to "anticipate" the contamination (the FDA was unaware that ZHP had actual knowledge at least as of July 27, 2017, ZHP SOMF ¶ 41.5, 47-51), and which resulted in a complete import ban on all ZHP products. (ZHP SOMF ¶ 46).

Additionally, Teva, and Torrent each violated their independent cGMP obligations to properly monitor their API supplier and to assure that the valsartan API they used was made in a cGMP-compliant manner and did not contain any NDMA or NDEA. Instead, both put their heads in the sand and relied on ZHP, which was selling them cheap valsartan API. (Teva SOMF ¶ 29-34, 81-95; Torrent SOMF ¶ 19-20, 50). For Teva, these violations include:

- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

For Torrent, they include:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

c. ZHP's, Teva's, and Torrent's VCDs Were Adulterated for Not Complying with Compendial Standards

Another independent basis for ZHP's, Teva's, and Torrent's breaches of their express warranties is that their VCDs failed to meet the compendial quality and purity requirements due to the NDMA and NDEA contamination. As to the API Manufacturer ZHP, the undisputed facts show that USP specifications did not permit NDMA or NDEA impurities in valsartan API. (ZHP SOMF ¶ 52, 136). Similarly, the Orange Book did not refer to, much less permit NDMA or NDEA impurities in valsartan finished-dose formulations, and the Orange Book requires that drug products "meet compendial [] standards" to qualify as AB rated therapeutic or generic equivalents. (ZHP SOMF ¶ 147-148). Yet, ZHP, Teva, and Torrent all admit that every single pill of their recalled VCDs contained NDMA or NDEA. (ZHP SOMF ¶ 26-34, 164-167; Teva SOMF ¶ 8-25; Torrent SOMF ¶ 16, 23, 24, 24(a), 24(b), 25, 48).

On these facts, no reasonable juror could find that ZHP's, Teva's, and Torrent's valsartan and VCDs met compendial standards, when those standards indisputably did not provide *any* allowance for *any* amount of NDMA or NDEA. Indeed, to comply with USP standards, USP requires manufacturers to characterize

their products' impurity profiles, including by conducting a "sound scientific appraisal of the chemical reactions involved in the synthesis of the drug substance[.]" **And when they modify the manufacturing process they are required to identify all impurities, via whatever analytical method is necessary to do so**. USP also requires:

> Nonmonograph tests and acceptance criteria suitable for detecting and controlling impurities that may result from a change in the processing methods or that may be introduced from external sources should be employed in addition to the tests provided in the individual monograph, where the presence of the impurity is inconsistent with good manufacturing practices or good pharmaceutical practices.

(ZHP SOMF ¶ 52). The undisputed evidence shows that the ZHP Defendants utterly and completely failed to conduct such an appraisal for their valsartan API. (ZHP SOMF ¶ 43-121; *see also* Teva SOMF ¶ 29-33, 60-6, 103-108).

Defendants could not legally sell their VCDs without fulfilling their warranties by selling the FDA approved pills with no NDMA or NDEA contamination, complying with the USP and the listing in the Orange Book. For the Orange Book, "[t]he main criterion for the inclusion of any product is that the product is the subject of an application with an approval." (ZHP SOMF ¶ 147). The Orange Book's "[a]pproved drug products are considered to be therapeutic equivalents." (*Id.*; *see also* 21 C.F.R. § 314.3). More specifically:

> FDA classifies as therapeutically equivalent those drug

> products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) **meet compendial or other applicable standards of strength, quality, purity, and identity**; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; **(4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations**.

(ZHP SOMF ¶ 147). Here, Defendants represented that their VCDs were FDA approved, USP compliant, and as AB rated in the Orange Book, meaning that they were represented to be therapeutically equivalent to the RLDs (Diovan and Exforge). (ZHP SOMF ¶ 147; Teva SOMF ¶ 37; Torrent SOMF ¶ 23, 26, 37, 57). Hai Wang confirmed that representation was made to all buyers. (ZHP SOMF ¶ 147-148). Since they neither met compendial standards nor were manufactured in compliance with CGMP, the ZHP, Teva, and Torrent VCDs were not therapeutic or generic equivalents as set forth in the Orange Book, in breach of their express warranties.

More generally, there is no reasonable dispute that the pills were not as approved, and were thus adulterated. *See Mylan Labs Ltd. v. U.S. Food & Drug Admin.*, 910 F.Supp.2d 299, 301 (D.D.C. 2012) (specifically discussing the USP monograph for valsartan, which predates the relevant time period here, and holding

"if a USP monograph exists for an approved drug, an ANDA referencing that drug must meet the standards set forth in the monograph to gain FDA approval"); *U.S. v. Lanpar Co.*, 293 F. Supp. 147, 153-54 (N.D. Tex. 1968) (**violation of USP renders a drug adulterated, misbranded, and illegal to introduce into inter-state commerce**) (citing 21 U.S.C. § 351, 352) (emphasis added). Thus, Defendants' sale of the adulterated and contaminated VCDs violated their express warranties.

d. ZHP's, Teva's, and Torrent's Valsartan API and VCDs Were All Contaminated with NDMA and/or NDEA

Even if Defendants' products were not adulterated (they were), were made in a cGMP-compliant manner (they were not), and complied with compendial standards (they did not), these Defendants still breached their express warranties because all of their valsartan API and VCDs were contaminated with genotoxic, probable human carcinogens NDMA or NDEA.

It is undisputed that before the recalls, ZHP, Teva, and Torrent never disclosed the presence of NDMA or NDEA in any of their products. (ZHP SOMF ¶ 41.5; Teva SOMF ¶ 39-40; Torrent SOMF ¶ 35-36, 41, 43). It is further undisputed that all of their valsartan API and VCDs contained NDMA and/or NDEA. (ZHP SOMF ¶ 26-34, 164-167; Teva SOMF ¶ 8-25; Torrent SOMF ¶ 23-24, 24(a), 24(b), 47-48). That each Defendant's product contained an undisclosed genotoxic substance that is a probable human carcinogen is itself a breach of their express affirmations.

This was clearly a material breach because NDMA and NDEA are genotoxic

impurities. (ZHP SOMF ¶ 33, 61-62, 86, 98, 115, 130-131, 135-144, 165, 167, 170). Teva and Torrent admitted the same. (Teva SOMF ¶ 97-102; Torrent SOMF 23, 47-48, 52, 55.) Those admissions reflect the regulatory classifications of those impurities. (ZHP SOMF ¶ 61, 62, 85-86, 130-131; Teva SOMF ¶ 102; Torrent SOMF ¶ 47, 53-56).

ZHP, Teva, and Torrent also admit that NDMA and NDEA are probable human carcinogens. (ZHP SOMF ¶ 34, 73, 136-137, 167; Teva SOMF ¶ 101; Torrent SOMF ¶ 47, 49, 52, 55). This is consistent with the IARC classification of NDMA and NDEA as probable human carcinogens published in 1987. (ZHP SOMF ¶ 136; Teva SOMF ¶ 102; Torrent SOMF ¶ 47). It is also consistent with the 2002 WHO peer-reviewed paper concluding that, "NDMA is highly likely to be carcinogenic to humans." (ZHP SOMF ¶ 136, 163.1). Indeed, ICH M7 (and predecessor versions of it relied on by FDA), as well as the 2008 FDA Guidance, have consistently identified n-nitroso compounds as in the "cohort of concern" as "high potency mutagenic carcinogens[.]" (ZHP SOMF ¶ 57-58, 61, 85-87, 130-131; Teva SOMF ¶ 98-100, 102; Torrent SOMF ¶ 52-53).

Of course, NDMA and NDEA are not listed as valsartan impurities in the USP monograph, the Drug Master Files or Abbreviated New Drug Applications, or the formulation of the RLDs in the Orange Book for Defendants' VCDs. This is because the RLD manufacturing process (the TIN process) was not capable of creating

NDMA or NDEA. (ZHP SOMF ¶ 10, 10.5, 12, 52, 126-134, 145-154.5; Torrent SOMF ¶ 35-37).

This is not a close call. ZHP agreed that it would be **unethical** to perform human studies on the carcinogenicity of NDMA, or to knowingly sell valsartan contaminated with NDMA. (ZHP SOMF ¶ 139, 163.1). ZHP's own press releases announcing its recalls explicitly stated that the contaminated valsartan was recalled because it presented an "unacceptable carcinogenic risk to the intended patient population." (ZHP SOMF ¶ 143, 155). This admission is of course a completely accurate statement corroborated by other undisputed evidence, and is dispositive.[8]

ZHP admitted: [redacted] (ZHP SOMF ¶ 159). Multiple ZHP witnesses agreed that nobody could have sold or bought the contaminated pills if the contamination was known. (ZHP SOMF ¶ 155-163.2). Teva and Torrent similarly admitted that their VCDs were not saleable due to the NDMA or NDEA contamination. (Teva SOMF ¶ 25; Torrent SOMF ¶ 49, 57). The very fact of each Defendants' recall of *all* of their contaminated

[8] The Gomm study of valsartan users showed a statistically significant increased risk for liver cancer due to the nitrosamine contamination, and concluded, "**The immediate recall of all potentially NDMA-contaminated valsartan drug products by regulatory authorities worldwide was necessary in order to protect public health.**" (ZHP SOMF ¶ 138).

VCDs establishes the contamination and the materiality of same.

The Court has already ruled that the presence of these genotoxins breached Defendants' warranties:

> **The Court finds that, for prescription drugs, the mere identifying and marketing a drug as THE generic equivalent to a branded pharmaceutical listed in the Orange Book and then selling that generic equivalent when it contains a contaminant not included in the Orange Book listing constitutes a breach of express warranty.** A marketed generic containing a contaminant cannot be the equivalent to the chemical entity listed in the Orange Book. Put simply, a seller cannot call its product "X" and sell it as "X" and then expect such identification not to create an express warranty that the product is "X".
>
> The Mfrs' very naming of the drug as valsartan or valsartan-containing amounted to an express warranty on which plaintiffs had no choice but to "rely" when they were prescribed the drug and bought it as a medication for their high blood pressure. **Plaintiffs did not have to "perceive" the package labelling or insert in order to create a benefit of the bargain. All they had to know was they were buying a generic drug that contained valsartan because the very name "valsartan" or "valsartan-containing" constituted itself an express warranty that what plaintiffs were purchasing was the chemical equivalent of the Orange Book pharmaceutical**. *See, e.g.*, *Gremo v. Bayer Corporation*, 469 F.Supp.3d 240, 258 (D.N.J. 2020) quoting "'A statement can amount to a warranty, even if unintended to be such by the seller, if it could fairly be understood ... to constitute an affirmation or representation that the [product] possesse[s] a certain quality or capacity relating to future performance.' *Volin v. General Electric Company*, 189 F. Supp. 3d 411, 420 (D.N.J. 2016) (citations omitted)."

In re Valsartan, Losartan, Irbesartan Prods. Liab. Litig., MDL No. 2875 (RBK-JS), 2021 WL 222776, at *11 (D.N.J. Jan. 22, 2021) (emphasis added) (ECF 775).

There is no factual dispute that Defendants' labeling and all marketing to buyers warranted that the valsartan they sold was FDA, USP compliant, and AB rated and thus the therapeutic equivalent of the RLD per the Orange Book – and affirmatively represented that there were no nitrosamine impurities therein. (ZHP SOMF ¶ 126-134, 145-154.5; Teva SOMF ¶ 34, 37; Torrent SOMF ¶ 32, 35-37). It was not as represented. The valsartan and VCDs were contaminated with highly toxic genotoxic probable human carcinogens. And if those warranties had not been given the valsartan could not have been sold or purchased.

Moreover, the retailer Defendants—the pharmacies that dispensed Defendants' VCDs which were paid for by consumers and TPPs—also confirmed that they would never knowingly sell adulterated drugs. (ZHP SOMF ¶ 144).

Thus, the only issue remaining for trial is the amount of damages.

B. The Same Undisputed Evidence Establishes Defendants' Violations of Consumer Protection Laws ("CPL") of CPL Subclass A

Under each state law of CPL Subclass A, the core elements include: (1) that the defendant engaged in the conduct proscribed by the act; (2) that the conduct occurred in trade or commerce; and (3) that the plaintiff suffered injury and damages as a result of the proscribed conduct. Plaintiffs address the core elements of all these similar state CPL claims in turn.

All of the CPL Subclass A states have standardized violation language (generally prohibiting "deceptive" or "unfair" practices), which language encompasses the ZHP, Teva, and Torrent Defendants' respective conduct. Indeed, the vast majority of the CPL Subclass A states explicitly instruct courts to incorporate guidance and decisional law made pursuant to the Federal Trade Commission Act ("FTC Act") as determinative in construing their own CPL laws (Alaska, Arizona, California, Connecticut, Florida, Hawaii, Louisiana, New York, New Hampshire, North Carolina, Washington).[9]

In turn, courts construing the FTC Act have consistently remarked, "[b]ecause the FTC Act is a remedial statute, [they] are guided by the familiar canon of statutory construction that remedial legislation should be construed broadly to effectuate its purposes." *Fed. Trade Comm'n v. AT&T Mobility LLC*, 883 F.3d 848, 854 (9th Cir.

[9] *Borgen v. A & M Motors, Inc.*, 273 P.3d 575, 583 (Alaska 2012); Arizona Rev. Stat. § 44- 1522(C); *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 543 (Cal. 1999); Conn. Gen. Stat. Ann. § 42-110b; Fla. Stat. Ann. § 501.204; Haw. Rev. Stat. Ann. § 480-2; *Cheramie Servs., Inc. v. Shell Deepwater Prod., Inc.*, 2009-1633 (La. 4/23/10), 35 So. 3d 1053, 1056 ("this 1972 [Louisiana] legislation was modeled after the [FTC Act]"); *F.T.C. v. Crescent Pub. Grp., Inc.*, 129 F. Supp. 2d 311, 318 (S.D.N.Y. 2001) ("Moreover, the [New York] state law is modeled in part on the FTCA and compliance with the FTCA is a defense to charges under the law."); N.H. Rev. Stat.Ann. § 358- A:13; *Johnson v. Phoenix Mut. Life Ins. Co.*, 266 S.E.2d 610, 620 (N.C. 1980) ("[I]t is appropriate for us to look to the federal decisions interpreting the FTC Act for guidance" in construing N.C. Gen. Stat. § 75-1.1); *State v. Living Essentials, LLC*, 436 P.3d 857, 866 (2019) ("Washington courts have repeatedly adopted federal court interpretations of section 5 of the FTCA when reviewing CPA cases.").

2018) (citations and internal quotations omitted). The Third Circuit has emphasized the FTC's ability to "deem a practice unfair [or deceptive]" under the FTC Act via its issuance of policy statements. *F.T.C. v. Wyndham Worldwide Corp.*, 799 F.3d 236 (3d Cir. 2015). The FTC has issued "Policy Statements" on both "unfairness" and "deception" that encompass the undisputed facts here, and those policy statements have been upheld by the courts (including specifically the Third Circuit in *Wyndham*).

1. Undisputed Evidence Establishes the "Deceptive" Conduct of the ZHP, Teva, and Torrent Defendants

To establish deception under the FTC Act, (1) there must be a representation, (2) the representation was likely to mislead customer acting reasonably under the circumstances, and (3) the representation must be material. *F.T.C. v. Millennium Telecard, Inc.*, No. 11cv2479, 2011 WL 2745963, at *3 (D.N.J. July 12, 2011) (Linares, J.) (citing authorities). The FTC has issued policy statements on deception that unambiguously cover the circumstances of this case. In its 1983 Policy Statement on Deception, the FTC stated that: "Practices that have been found misleading or deceptive in specific cases include false oral or written representations … **sales of hazardous or systematically defective products [] without adequate disclosures** … and **failure to meet warranty obligations**." (Oct. 14, 1983 FTC Policy Statement on Deception ("the FTC Deception Policy Statement (emphasis added) (attach as Ex. 124 to Adam M. Slater's Certification in Support of this

Motion).).

The undisputed facts establish that the Defendants made ***false written representations*** that their VCD products; were FDA-approved, generic valsartan-containing versions of DIOVAN and EXFORGE; met the compendial standards and were the therapeutic equivalent of the brand name drugs as listed in the Orange Book, including the embedded representations contained therein.[10] (ZHP SOMF ¶ 10, 10.5, 12, 52, 126-134, 145-154.5; Teva SOMF ¶ 37-40; Torrent SOMF ¶ 32-37).

The required actions when the contamination was disclosed are very telling: the Defendants recalled their VCDs, admitted they were all contaminated with probable human carcinogens NDMA/NDEA, and even stated publicly that their VCDs represented an "unacceptable carcinogenic risk." (ZHP SOMF ¶ 143, 155; Torrent SOMF ¶ 21, 47-49; *see also* Teva SOMF ¶ 102). The FDA determined that the Defendants' VCDs were adulterated as a direct result of "significant" CGMP violations, and therefore as a matter of law they were illegal to sell. *See* 21 U.S.C. § 331(a) & (b). These undisputed acknowledgments and findings establish that the Defendants' VCDs were hazardous or systematically defective, and it is further undisputed that the Defendants "sold" those products "without adequate disclosures"

[10] For example, as discussed *supra*, to be eligible for Orange Book certification, the Orange Book requires that the subject pharmaceuticals both meet "compendial [] standards" and be "manufactured in compliance with Current Good Manufacturing Practices regulations." (*See* https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last visited Dec. 13, 2023).)

(indeed, the Defendants admittedly made no disclosure of the presence of these carcinogens in their drugs).

Accordingly, for those CPL Subclass A states that incorporate FTC interpretations and related decisional law, Defendants' liability for their deceptive practices is established as a matter of law.

For those states that do not expressly look to FTC Act guidance (again, this is Missouri,[11] Nebraska,[12] Oklahoma,[13] Oregon,[14] Pennsylvania[15]), the very same

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[11] Missouri's CPL "broadly" prohibits "deception" and deliberately has not defined that term to promote the remedial purposes of the statute. *Kelly v. Cape Cod Potato Chip Co.*, 81 F. Supp. 3d 754, 759 (W.D. Mo. 2015) (citing and quoting cases).

[12] Nebraska defines deception possessing the tendency to mislead, without regard to any materiality requirement. *Raad v. Wal-Mart Stores, Inc.*, 13 F. Supp. 2d 1003, 1018 (D. Neb. 1998).

[13] Oklahoma's CPL prohibits both unfair and deceptive practices, and defines "deceptive" as "a misrepresentation, omission or other practice that has deceived or could reasonably be expected to deceive or mislead a person to the detriment of that person.". Okla. Stat. tit. 15, §§ 753, 752(13), (14).

[14] Oregon's "unconscionability" standard includes deception as this Court has previously found. (ECF 2261, App'x I, at 26 (citing and quoting *State ex rel. Rosenblum v. Johnson & Johnson*, 62 P.3d 1197 (Ore. Ct. App. 2015), *aff'd* 358 Or. 611 (Ore. 2016) ("A material risk that a product has a latent defect is exactly the kind of inherent feature of a product implicated under ORS 646.608(1) and (2).").)

[15] Pennsylvania's enumerated deceptive practices include TPP Trial Defendants' conduct, These include, *inter alia*, "representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another[;]" "representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have[;]" "[c]ausing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services[;]" or "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding[.]" Pa. Cons. Stat. § 201-1, 201-2, & 201-3; *see also Gregory v. Metro Auto Sales, Inc.,* 158 F.Supp.3d 302 (E.D. Pa. 2016) (Under Pennsylvania

result is reached based on the same evidence and same analysis.

2. *Undisputed Evidence Establishes the "Unfair" Conduct of the ZHP, Teva, and Torrent Defendants*

In *F.T.C. v. Wyndham*, the Third Circuit was tasked with interpreting the "unfairness" prong of the FTC Act. In doing so, the Court used the FTC's 1980 Policy Statement on "Unfairness" as its guide. 799 F.3d at 243-247. (See: Dec. 17, 1980 FTC Policy Statement on Unfairness ("the FTC Unfairness Policy Statement" (attach as Ex. 125 to Adam M. Slater's Certification in Support of this Motion). The Court described the three-factor unfairness test: (1) the substantiality of the injury; (2) whether it was outweighed by any countervailing benefits; and (3) whether consumers [or in this case, reimbursing TPPs] could have reasonably avoided the injury. *Id.* The Third Circuit has recognized that – for purposes of construing the FTC Act – a practice may be "both deceptive and unfair[,]" that "the facts relevant to unfairness and deception claims frequently overlap…" 799 F.3d at 245 & n.4.

Tracking these criteria, the key facts are undisputed: the Defendants' VCDs were adulterated due to their contamination with non-approved, genotoxic, probable human carcinogens – NDMA and NDEA. (ZHP SOMF ¶ 33-34, 52, 61-62, 73, 86, 98, 115, 126-163.2, 165, 167, 170; Teva SOMF ¶ 8-25, 103-108; Torrent SOMF ¶

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law, courts should liberally construe the Unfair Trade Practices and Consumer Protection Law (UTPCPL) in order to effect the legislative goal of consumer protection).

23-24, 24(a), 24(b), 47-48, 53).

The Defendants' corporate representatives agreed that the contaminating impurities at issue, NDMA and NDEA, were genotoxic, probable human carcinogens. (ZHP SOMF ¶ 33, 61-62, 73, 85-86, 98, 115, 130-131, 135-144, 165, 167, 170; Teva SOMF ¶ 97-102; Torrent SOMF ¶ 52-56). The Defendants then recalled every single pill within expiry of their at-issue VCDs because, in the words of ZHP, they presented, "an unacceptable carcinogenic risk." (ZHP SOMF ¶ 143-143.5, 155, 160, 167; Teva SOMF ¶ 102; Torrent SOMF ¶ 47–49). The Court has described what happened in clear terms, in granting Plaintiffs' Motion for Class Certification:

> Defendants may be hard pressed to refute that their conduct resulted in nitrosamine contamination of VCDs; it's incontrovertible that the FDA recalled lots and batches of presumed-contaminated VCDs for several years. It is further incontrovertible in the morass of factual and legal arguments here that the contamination resulted from defendants' non-compliance of cGMPs at some level. Since defendants' conduct in making contaminated VCDs and in putting these into the U.S. drug supply chain, which plaintiffs paid for, is incontrovertible, that singular fact grounds all of plaintiffs' claims.

(ECF 2261, at 21).

The resulting sale into the stream of commerce of millions of adulterated pills, containing unapproved, genotoxic probable human carcinogens, which presented an "unacceptable carcinogenic risk," clearly satisfies the requirement to demonstrate a

substantial injury.

There is certainly no countervailing benefit. Adulterated drugs cannot legally be sold. 21 U.S.C. § 331. Similarly, ZHP told the world that the pills were recalled due to the "unacceptable carcinogenic risk." (ZHP SOMF ¶ 143, 155). Any argument that selling the pills under these circumstances provided a countervailing benefit is specious, as the Court has routinely found.[16] In fact, the Court has already determined, at the pleadings stage, that the VCDs are "economically worthless … regardless of whether the sold VCDs actually achieved the medical purpose of lowering blood pressure" as set forth above. (ECF 775, at 20).[17]

Finally, it is undisputed that the Plaintiffs could not have reasonably avoided the injury, since there was no way for them to know that the purported FDA approved drugs they were buying were actually contaminated with genotoxic,

[16] The Court has struck the opinions of Defendants' experts who have attempted to offer such testimony. (ECF 2261, at 77-79 (striking opinions of Dr. Punam Keller) & ECF 1958 (striking opinions of Dr. John Flack)).

[17] *Debernardis v. IQ Formulations, Inc.,* 942 F.3d 1076, 1088 (11th Cir. 2019) (determining that adulterated dietary supplements are economically worthless); *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 524 (6th Cir. 2015) ("Whether purchasers were nevertheless satisfied with Align does not affect the propriety of a full-refund damages model."); *In re Amla Litig.*, 282 F. Supp. 3d 751, 756, 767 (S.D.N.Y. 2017); *Steroid Hormone Prod. Cases*, 181 Cal. App. 4th 145, 150-159 (2010) (approving full refund damages model where supplements were contaminated finding "in this case [Plaintiff] does not put valuation at issue when he alleges that he bought a product that was illegal to sell or possess."); *Krueger v. Wyeth, Inc.*, 2011 WL 897144, at *2 (S.D. Cal. Mar. 30, 2011) (approving full refund model despite evidence that doctors continued prescribing drug and that plaintiff *continued taking the drug* even after becoming aware of health risks).

probable human carcinogens, that rendered the pills adulterated. At all times, the Defendants represented and sold their VCDs as FDA-approved "valsartan" therapeutically equivalent to the RLDs, and meeting compendial and Orange Book standards for generic interchangeability, as set forth *supra*.

In this context, Defendants are also trapped by their own overreaching disclaimers (even though Plaintiffs dispute them). Defendants claim they did not know, and could not have known of the NDMA/NDEA contamination. For instance, all three of the Defendants assert in their recently filed Answers that *not even they* could have known of the contamination prior to recall. (ECF 2547, 2548, 2549.) The ZHP Defendants assert that they "did not know – and could not reasonably have known" of the NDMA/NDEA contamination. (ECF 2549, 64 (Affirmative Defense titled "Defendants' Good Faith"). While these defenses are meritless, Defendants are nevertheless estopped from claiming that the TPP Class Members could have reasonably known and avoided reimbursing for their products when they claim that was not knowable even to themselves as the manufacturers.

Accordingly, for all of the CPL Subclass A states that look to the FTC Act, the Defendants' conduct is "unfair" based on undisputed common evidence.

Even for the small minority of states that do not *expressly* incorporate FTC Act "unfairness" guidance (Missouri, Nebraska, Oklahoma, Oregon,

Pennsylvania),[18] the very same result is reached. For instance, Missouri's CPL does not define "unfair practice" as that term is used in Missouri's CPL, but that choice was deliberate to "promote" its "fundamental purpose" of protecting consumers. *Kelly v. Cape Cod Potato Chip Co.*, 81 F. Supp. 3d 754, 759 (W.D. Mo. 2015) (citing and quoting authorities). These statutes are deliberately broad and flexible to meet their remedial purpose and all proscribe "unfair" conduct. *See also State ex rel. Stenberg v. Consumer's Choice Foods*, 755 N.W.2d 583 (Neb. 2008) (stating that the Nebraska "CPA is equitable in nature" and that the statute "does not define 'unfair' or 'deceptive'" as those terms are used and adopting an open-ended standard of unfairness as offending an "established concept of unfairness"); Okla. Stat. Ann. tit. 15, § 752 ("'Unfair trade practice' [under Oklahoma CPL] means any practice which offends established public policy or if the practice is … unscrupulous or substantially injurious to consumers")[19]; *Gordon v. Rosenblum*, 393 P.3d 1122, 1126-28 (Ore. 2017) (defining "unconscionable" as that term is used in Or. Rev. Stat. Ann. § 646.607 to mean "*unfair*, unjust, or shocking to the conscience" and

[18] Plaintiffs do not pursue an "unfair" practices claim under North Dakota's Unfair Trade Practices Law, N.D. Code § 51-10-01 *et seq.* because the statute does not provide a private right of action. *Trade 'N Post, L.L.C. v. World Duty Free Americas, Inc.*, 628 N.W.2d 707, 710 (N.D. 2001). Plaintiffs' "deceptive" acts claim is made pursuant to the Unlawful Sales or Advertising Practices Act, N.D. Code § 51-15-01 *et seq*.

[19] *Robinson v. Sunshine Homes, Inc.*, 291 P.3d 628 (Okla. Civ. App. Div. 1 2010) (stating that the Oklahoma Consumer Protection Act is remedial in nature and is to be liberally construed to effectuate its underlying purpose).

emphasizing that "unconscionability is an equitable doctrine" (emphasis added)); Pa. Cons. Stat. § 201-1-201-3 (prohibiting "unfair or deceptive acts or practices" and defining that phrase in ways that would undisputedly cover the Defendants' actions).[20] The analysis presented above clearly satisfies these renditions of the standard.

3. Intent Is Not Required for CPL Subclass A States

Nor is intent required to establish the Defendants' liability under any of the CPL Subclass A states' laws.[21] Accordingly, the legal fact of deceptive or unfair

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[20] *See supra* at n.14.

[21] *See Borgen v. A&M Motors, Inc.*, 273 P.3d 575, 591 (Alaska 2012); *State ex rel. Babbit v. Goodyear Tire & Rubber Co.*, 626 P.2d 1115, 1118 (Ariz. Ct. App.1981); *Prakashpalan v. Engstrom, Lipscomb & Lack*, 223 Cal. App. 4th 1105, 1133 (Cal. App. 2nd Dist. 2014); *Lawrence v. Richman Group Capital Corp.*, 358 F. Supp. 2d 29 (D. Conn. 2005); *PNR, Inc. v. Beacon Prop. Mgmt., Inc.*, 842 So.2d 773, 777 (Fla. 2003); *Morice v. Hosp. Serv. Dist. #3*, 430 F. Supp. 3d 182, 216 (E.D. La. 2019) (A misrepresentation is "deceptive" for purposes of LUTPA); *Duncan v. Savannah, LLC*, 637 S.W.3d 633, 643 (Mo. Ct. App. 2021) ("It is the defendant's conduct, not his intent, which determines whether a violation has occurred." (citations and quotations omitted)); *Raad v. Wal-Mart Stores, Inc.*, 13 F. Supp. 2d 1003, 1014 (D. Neb. 1998) ("practice possessed the tendency or capacity to mislead"); ECF 2261, App'x I, at 20 (this Court stating, with respect to New Hampshire law, that the "P[laintiffs] could claim violation under several enumerated prohibitions by D[efendant]s in the statute that do not require scienter."); *Pension Fund v. Marine Bank*, 85 N.Y.2d 20, 26 (N.Y. 1995); *Myers v. Liberty Lincoln-Mercury, Inc.*, 365 S.E.2d 663, 664 (N.C. 1988) ("purchaser of misrepresented merchandise does not have to prove fraud, bad faith or intentional deception"); *DJ Coleman, Inc. v. Nufarm Americas, Inc.*, 693 F. Supp. 2d 1055 (D.N.D. 2010); *Trotter v. Am. Mod. Select Ins. Co.*, 220 F. Supp. 3d 1266, 1269 (W.D. Okla. 2016); *State ex rel. Rosenblum v. Johnson & Johnson*, 362 P.3d 1197, 1203 (2015); *Gregg v. Ameriprise Fin., Inc.*, 245 A.3d 637, 650 (Pa. 2021); *State v. A.N.W. Seed Corp.* 802 P.2d 1353 (Wash. 1991).

conduct on the part of the Defendants is sufficient to establish liability without regard to the Defendants' respective states of mind when engaging in the conduct.

4. All Other Incidental Elements of the CPL Subclass A Claims Are Satisfied

The remaining liability elements of these claims are mostly *pro forma* and undisputed. For example, one is that the practices occurred in the context of trade or commerce. The answer there is undisputedly "yes." Another occasional element for some of the CPL Subclass A states is that the conduct affect the public interest. The answer there is likewise indisputably "yes" based on the same proof Plaintiffs will introduce in meeting the substantiality of injury element of the "unfair" prong. There is a strong public interest in ensuring that prescription pharmaceuticals are free of harmful contaminants, especially those that have been found to be potent genotoxic carcinogens that render the drugs adulterated. Finally, TPPs also have standing to sue under all of the CPL Subclass A states.[22]

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[22] *State v. O'Neill Investigations, Inc.*, 609 P.2d 520, 535 (Alaska 1980); *Waste Mfg. & Leasing Corp. v. Hambicki*, 900P.2d 1220, 1224 (Ariz. Ct. App.1995 *BladeRoom Grp. Ltd.* v. *Facebook, Inc.*, 219 F. Supp. 3d 984, 995 (N.D. Cal. 2017); *Hydro Air of Connecticut, Inc. v. Versa Technologies, Inc.*, 599 F.Supp. 1119 (D. Conn. 1984); *State Farm Mutual Automobile Insurance Company v. Health and Wellness Services, Inc*., 389 F.Supp.3d 1137 (S. D. Fla. 2018); Haw. Rev. Stat. § 480-13 (standing to sue for "unfair" conduct); La. Rev. Stat. § 51:1402(8); Mo. Rev. Stat. §§ 407.010 (defining "person" to include businesses) and 407.025 (granting cause of action to "persons" but with the limitation that the subject of the claim have been "merchandise *primarily* for personal, family, or household purposes"); Neb. Rev. Stat. § 59-1601; *George v. Al Hoy & Sons, Inc.*, 27 A.3d 697, 704 (N.H. 2011) ("Thus, by its plain language, the CPA clearly provides a private right of action to

5. Damages Will Be Proven at Trial

Since this Motion only relates to liability, Plaintiffs intend to prove their damages (including any applicable civil penalties) at trial.

CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' motion for partial summary judgment, finding that:

1. ZHP, Teva, and Torrent made express warranties that the valsartan API and finished dose they sold was the FDA approved formulation, manufactured in compliance with cGMPs, and compliant with all compendial requirements.

2. ZHP, Teva, and Torrent breached those express warranties because the valsartan API and finished dose they sold contained the genotoxic, probable human carcinogens NDMA and NDEA, was not the FDA approved formulation, was not manufactured in compliance with cGMPs, was not complaint with all compendial requirements, and was thus adulterated and presented an "unacceptable carcinogenic risk."

3. But for the warranties, the adulterated valsartan API and finished dose, presenting an "unacceptable carcinogenic risk," could not have been sold, or paid for by the TPPs.

4. The remaining issue on breach of express warranty for trial is the amount of damages sustained by the TPPs.

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business entities."); *Vitolo v. Dow Corning Corp*., 634 N.Y. S.2d 362, 366 (Sup. Ct. 1995) (noting statute "gives any person who has been injured due to a violation thereof the right to bring an action. The definition of 'person' is much broader than 'consumer,' embracing all possible plaintiffs, including business persons"); N.C. Gen. Stat. § 75-16; *Staal v. Scherping Enters., Inc.*, 466 F.Supp. 3d 1030,1034 (D.N.D.2020) (North Dakota statute not limited solely to "consumer" transactions); Okla. Stat. tit. 15, § 752; Or. Rev. Stat. § 646.605; 73 Pa. Cons. Stat. § 201-1; Wash. Rev. Code § 19.86.010.

5. ZHP, Teva, and Torrent violated the liability provisions of the applicable consumer protection laws due to their deceptive/unfair conduct.

6. But for the deceptive/unfair conduct of ZHP, Teva, and Torrent, the adulterated valsartan API and finished dose, presenting an "unacceptable carcinogenic risk," could not have been sold, or paid for by the TPPs.

7. The remaining issue on the consumer protection laws for trial is the amount of damages sustained by the TPPs.[23]

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Respectfully submitted,

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[23] As set forth at the outset, the relief sought with regard to the fraud claims against ZHP and Torrent is set forth in the separate briefs addressing those motions.

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